SIEMENS

PATENT
Attorney Docket No. 2003P17536WOUS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Inventor:	Michael Maschke	Group Art Unit:	3777
Serial No.:	10/587,671	Examiner:	J. F. Brutus
Filed:	July 27, 2006	Confirmation No.:	8478
Title	DEVICE AND METHOD FOR TAKING A HIGH ENERGY IMAGE		

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APPELLANTS' BRIEF UNDER 37 CFR 41.37

Sir:

This brief is in furtherance of the Notice of Appeal filed in this application on 23 September 2011.

1. REAL PARTY IN INTEREST - 37 CFR 41.37(c)(1)(i)

The real party in interest in this Appeal is the assignee of the present application, Siemens Aktiengesellschaft.

2. RELATED APPEALS AND INTERFERENCES - 37 CFR 41.37(c)(1)(ii)

There is no other appeal, interference or judicial proceeding that is related to or that will directly affect, or that will be directly affected by, or that will have a bearing on the Board's decision in this Appeal.

3. STATUS OF CLAIMS - 37 CFR 41.37(c)(1)(iii)

Claims canceled: 1 – 10.

Claims withdrawn but not canceled: None.

Claims pending: 11 - 24.

Claims allowed: none.

Claims rejected: 11 - 24.

The claims on appeal are 11 - 24. A copy of the claims on appeal is attached hereto in the Claims Appendix. Appellants respectfully appeal the final rejection of claims 11 - 24.

4. STATUS OF AMENDMENTS - 37 CFR 41.37(c)(1)(iv)

No amendment has been made to the claims since the mailing of the second Final Office Communication on 24 May 2011. A response without claim amendment was filed on 20 July 2011, but the rejections were sustained per the Advisory Action mailed 23 August 2011.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER- 37 CFR 41.37(c)(1)(v)

With reference by page and line number to the detailed description, and with reference to the figures, the following summary describes one or more exemplary embodiments disclosed in the Specification and which are covered by one or more specific claims, but it is to be understood that the claims are not so limited in scope.

5A. CONCISE EXPLANATION OF SUBJECT MATTER DEFINED IN INDEPENDENT CLAIM 11.

With reference to Figure 1, **independent claim 11** is directed to a medical device 1 (e.g., an x-ray system) for taking a high energy image of an object (e.g., patient body region) under a medical examination into which an adjuvant is insertable. Page 3, lines 9 - 13; page 4, line 13.

The device includes an x-ray imaging unit (x-ray detector 3 and image processing unit 6) for taking the high energy image of the adjuvant inserted within the object. See page 4, lines 15 - 17 and 24 - 27. See, also, page 1, line 29 – page 2, line 7; and page 7, lines 1 – 13. A control unit 7 controls the taking of the high energy image. Page 5, lines 1 - 3. The control unit 7 is supplied with an identification code of the adjuvant via an input device and is coupled to set operating parameters of the image unit according to the identification code. (page 5, lines 7 - 13; page 2, line 29 - page 3, line 7; page 3, lines 11 - 17) to control contrast between the adjuvant and an adjacent region of the object in the high energy image. Page 7, lines 15 – 20; and page 2, line 29 – page 3, line 13.

5B. CONCISE EXPLANATION OF SUBJECT MATTER DEFINED IN INDEPENDENT CLAIM 20.

With reference to Figures 2 - 4 and 7, **independent claim 20** is directed to a method for taking a high energy image (e.g., with an x-ray system) of an object (e.g., patient body region) under medical examination containing a medical adjuvant. Page 3, lines 9 - 13. The taking of the high energy image is controlled by an imaging unit via a control unit (image processing unit 6 and system controller 7). See page 4, lines 24 - 27; page 5, lines 1 - 3. An identification code of the medical adjuvant is input into the control unit. Page 5, lines 7 - 13. See, also, page 7, lines 4 - 8 and Figure 3 which references inputting 30 of the identification code. Operating parameters of the imaging unit are set via the control unit according to the identification code. Page 5, lines 7 - 13 and reference to database 12; page 5, line 19 - page 6, line 22. The high energy image is taken by the imaging unit. Page 3, lines 11 - 13; page 7, line 10. A high energy image is taken of the adjuvant inserted and a region of the object with the imaging unit (page 2, line 29 - page 3; page 3, lines 11 - 13; page 7, line 10) wherein the identification code is used by the control unit to control contrast between the adjuvant and the region of the object in the high energy image. Page 7, lines 15 – 20; and page 2, line 29 – page 3, line 13.

6. GROUNDS OF REJECTION TO BE REVIEWED UPON APPEAL - 37 CFR 41.37(c)(1)(vi)

1. Whether claims 11 – 15, 19, 21 and 24 are unpatentable under 35 U.S.C. over Banik (US2005/0197536) in view of Malackowski (US2004/0267297) and further in view of Pronk (U.S. 6,907,104) and still further in view of Whipple (US2003/0230630);

2. Whether claims 16 – 17 and 22- 23 are unpatentable under 35 U.S.C. over Banik (US2005/0197536) in view of Malackowski (US2004/0267297) and further in view of Pronk (U.S. 6,907,104) and still further in view of Whipple (US2003/0230630) and still again further in view of Binkert (2003/0197734); and

3. Whether claim 18 is unpatentable under 35 U.S.C. over Banik (US2005/0197536) in view of Malackowski (US2004/0267297) and further in view of Pronk (U.S. 6,907,104) and still further in view of Whipple (US2003/0230630) and still again further in view of Anderson (U.S. 6,394,952).

7. ARGUMENT 37 CFR 41.37(c)(1)(vii)

APPELLANTS TRAVERSE ALL REJECTIONS BASED IN WHOLE OR PART ON BANIK (US2005/0197536) IN VEW OF MALACKOWSKI (US2004/0267297 AND FURTHER IN VIEW OF PRONK (U.S. 6,907,104) AND STILL FURTHER IN VIEW OF WHIPPLE (US2003/0230630).

Patentability of Each Claim is to be Separately Considered

Appellants urge that, to the extent the claims are separately argued, patentability of each claim should be separately considered. General argument, based on deficiencies in the rejection of the independent claims 11 and 20 demonstrates patentability of all dependent claims. However, none of the rejected claims stand or fall together because each dependent claim further defines a unique combination that patentably distinguishes over the art of record. For this reason, the Board is requested to consider all argument presented with regard to each dependent claim.

To the extent provided, argument demonstrating patentability of each dependent claim is presented under subheadings identifying each claim by number.

General Basis To Overturn All Rejections Under Section 103

In order to sustain the rejections under Section 103, MPEP §2143 provides that three criteria must be met to establish a prima facie case of obviousness. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one skilled in the art, to modify the reference or to combine teachings of the references. Second, there must be a reasonable expectation of success. Third, the prior art must teach or suggest **all** of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must be both found in the prior art and not in the applicant's disclosure.

Therefore it is both fundamental and essential that the rejection be based on something more than a piecemeal combination of elements found among different prior art references. Yet this appeal is made because there is no suggestion or motivation in the prior art to modify the references and provide all of the features and functions recited in each claim. A mere assemblage of components taken from the prior art without a motivation to so reconstruct the prior art does not create a prima face case of obviousness. Rather, such an assemblage is a hindsight reconstruction which is not, in itself, a legitimate basis to reject claims as obvious.

7A. APPELLANTS TRAVERSE THE REJECTION OF INDEPENDENT CLAIMS 11 and 20 BASED ON BANIK (US2005/0197536) IN VEW OF MALACKOWSKI (US2004/0267297) AND FURTHER IN VIEW OF PRONK (U.S. 6,907,104) AND STILL FURTHER IN VIEW OF WHIPPLE (US2003/0230630).

7A(1). THE REJECTION OF INDEPENDENT CLAIM 11 UNDER SECTION 103 BASED ON BANIK IN VEW OF MALACKOWSKI AND FURTHER IN VIEW OF PRONK AND STILL FURTHER IN VIEW OF WHIPPLE IS IN ERROR.

Appellant submits that the art rejection of claim 11 is no more than a contrived effort to perform a piece meal reconstruction of that which is non-obvious. Further the rejection does not and cannot identify every feature of independent claim 11 and the claims which depend therefrom. Specifically, absence of the following features in the prior art renders the rejection invalid:

disclosure of an adjuvant;

supplying an identification code of an adjuvant to control the taking of the high energy image;

setting operating parameters of an image unit according to the identification code to control contrast; and

controlling the contrast between the adjuvant and an adjacent region of the object in the high energy image.

Claim 11 is directed to a medical device for taking an image of an object under medical examination "into which an adjuvant is insertable ... " The claim expressly requires:

an **x-ray imaging unit** for taking the x-ray image ***of the adjuvant inserted within the object***; and
a control unit ... *supplied with* ***an identification code of the adjuvant.***

Claim 11 requires that the control unit is coupled **to set operating parameters** of the image unit according to the identification code ***to control contrast*** between the adjuvant and an adjacent region of the object in the high energy image. It is respectfully urged that that even when the prior art is combined and modified per the rejection, the combination still fails to provide these features.

The rejection cites the Banik reference for disclosing gain control in a subsystem 114 that controls the taking of an endoscopy image. Paragraph [0084] is relied upon in this regard, but that paragraph only discloses a CMOS image sensor (not an x-ray imaging unit) in a system where gain control is implemented by adjusting current supplied to LEDs and gains applied to signals. The rejection appears to imply that CMOS image sensor is interchangeable with an x-ray unit and that achievement of a desired contrast with an x-ray is equivalent to adjustment of a gain control for a CMOS image sensor. Yet there is no support in the rejection for such a contention and there is no basis to assume such.

The rejection also indicates that the Banik reference could "prompt" for "operating parameters" for instruments at paragraph [0094] but, as best understood, this is totally incorrect. The paragraph refers to some type of inventory identification to track which tools are inserted into a working channel of an endoscope and to record information concerning the use of the tools during a procedure. None of this appears relevant at all to use of ***an identification code of the adjuvant*** to **set operating parameters** ***to control contrast*** between an adjuvant and an adjacent region of an object in an **x-ray image**. In summary, the rejection has construed paragraph [0094] of Banik totally out of context. The cited paragraph [0094] refers to a chip (tag) 62 in a cutting accessory 24 which can indicate, for example, an operating speed of the tool or, perhaps, use time for the tool. See paragraphs [0066] – [0071]. None of this concerns use of a

"control unit supplied with an identification code of the adjuvant ... to control contrast between the adjuvant and an adjacent region of the object in the ... [x-ray] image."

The rejection also argues (incorrectly) that the Banik reference discloses at paragraphs [0073].[0074] and[0084] adjustment of imager parameters such as gain or intensity of LED image sensors "based on inserted tools ..." There is absolutely no basis for such a conclusion and it is, at best, speculation.

In response to such deficiencies in the rejection, the Advisory Action (mailed 8/23/2011) states that the Examiner relies on the Pronk reference for disclosing a computer that sets and controls an x-ray imaging device on patient specific information such as a body part to be examined. Appellant urges that this prior art does not at all render the claimed invention obvious because none of the prior art addresses a contrast adjustment in an image based on properties of an adjuvant present in an image of, for example, a portion of a patient's body. Appellant teaches such use of specific information relating to the adjuvant which can enhance the contrast between the adjuvant and other portions of the image.

It is only the Appellant who recognizes that operating parameters for an image to be taken with an adjuvant can be associated with an identification code of the specific adjuvant. None of the other art citations compensate for the deficiencies in the Banik and Pronk references.

For example, the disclosure of Malackowski as described in the rejection and in the Advisory Action does not at all relate to setting

operating parameters of the image unit according to the identification code [of the adjuvant] to control contrast between the adjuvant and an adjacent region of the object ...

The rejection erroneously applies the Whipple reference as though it provides disclosure in the Abstract of Whipple for disclosure of "a code [which] has instructions to control image contrast ..." It is not seen that any disclosure relating to the bar code images described in the abstract of Whipple relate to controlling image contrast and, even if there were such disclosure, this would have nothing to do with controlling contrast between an adjuvant and surrounding regions (as asserted in the Advisory Action) in an x-ray image!

More fundamentally, the rejection is flawed because (contrary to the reassertion made in the Advisory Action) there is no motivation to combine any of this prior art in a manner which results in the claimed invention. There cannot be a legitimate combination because there is no recognition in any of the prior art of the teachings which Appellant has provided. Instead, the rejection is a blatant attempt in hindsight to reconstruct the invention of claim 11 by suggesting that certain ones of the claimed features could be provided by the prior art.

Based on a full reading of the art rejection, it appears that the Examiner is only arguing that the prior art could, if modified, perform in accord with claim 11. This is not what the law on obviousness is based on. The Examiner's speculations do not imply that one skilled in the art would have knowledge and motivation to so modify the prior art.

Despite argument to the contrary, the rejection of claim 11 sorely lacks explanation as to how one could possibly meet the above-quoted terms based on the Examiner's combination. It is not at all apparent how the references can be combined to render independent claim 11 obvious. There is no demonstration as to where, among any or all of the references, one could possibly find the features of

a control unit which controls the taking of the high energy image, the control unit supplied with an identification code of the adjuvant via an input device and coupled to set operating parameters of the image unit according to the identification code to control contrast between the adjuvant and an adjacent region of the object in the high energy image.

Further, there is no relation between any of the prior art (alone or in combination) and Appellant's teaching of setting operating parameters of an x-ray image unit according to the identification code assigned to an adjuvant. For at least the above-noted reasons, the rejection of claim 20 and each claim which depends therefrom should be overturned.

7A(2). THE REJECTION OF INDEPENDENT CLAIM 20 UNDER SECTION 103 BASED ON BANIK IN VEW OF MALACKOWSKI AND FURTHER IN VIEW OF PRONK AND STILL FURTHER IN VIEW OF WHIPPLE IS IN ERROR.

For reasons similar to those presented in the foregoing patentability argument for claim 11, the rejection of claim 20 and each claim which depends therefrom should also be overturned. Appellant hereby incorporates by reference all argument presented in Section 7A(1) as applied to claim 11 to this argument for application to claim 20.

Claim 20, directed to a method for taking a high energy image of an object under medical examination containing a medical adjuvant, requires:

> inputting an identification code of the medical adjuvant into the control unit;
> setting operating parameters of the imaging unit via the control unit according to the identification code … and
> taking a high energy image of the adjuvant inserted and a region of the object with the imaging unit …

Appellant submits that the art rejection of claim 20 is no more than a contrived effort to perform a piece meal reconstruction of that which is non-obvious. The rejection does not and cannot identify every feature of independent claim 20 and the claims which depend therefrom.

Specifically, absence of the following features in the prior art rejection renders the rejection invalid:

> a medical adjuvant;
> inputting an identification code of the medical adjuvant into the control unit; and

setting operating parameters of the imaging unit via the control unit according to the identification code.

In fact, none of the prior art recognizes benefits according to the invention of enabling adjuvants (e.g., stents) present in an object (e.g., a body portion) to be displayed with good contrast. Thus, if for no other reason, this combination of features cannot be reconstructed from the prior art. None of the applied art relates to an adjuvant or discloses association of an identification code of an adjuvant with any setting of operating parameters to control contrast for an imaging unit. In this regard, claim 20 expressly requires that:

"the identification code is used by the control unit to control contrast between the adjuvant and the region of the object in the high energy image."

Based in part on argument made against the rejection of claim 11, it can be said that, at best, the rejection only goes so far as to argue that all of this is obvious. The rejection cites the Banik reference for disclosing gain control in a subsystem 114 that controls the taking of an endoscopy image. Paragraph [0084] is relied upon in this regard, but that paragraph only discloses a CMOS image sensor (not an x-ray imaging unit) in a system where gain control is implemented by adjusting current supplied to LEDs and gains applied to signals.

The rejection also indicates that the Banik reference could "prompt" for "operating parameters" for instruments at paragraph [0094] but, as already noted, this is totally incorrect. The paragraph refers to some type of inventory identification to track which tools are inserted into a working channel of an endoscope and to record information concerning the use of the tools during a procedure. None of this appears relevant at all to use of ***an identification code of the adjuvant*** via an input device ... to set operating parameters ... to control contrast between the adjuvant and an adjacent region of the object in the high energy image.

In summary, the rejection has construed paragraph [0094] of Banik, totally out of context. The cited paragraph refers to a chip (tag) 62 in a cutting accessory 24 which can indicate, for example, an operating speed of the tool or, perhaps, use time for the tool. See paragraphs [0066] – [0071]. None of this concerns use of a

control unit ... supplied with an identification code of the adjuvant ... to set operating parameters ... to control contrast ...

The rejection also argues (incorrectly) that the Banik reference discloses at paragraphs [0073], [0074] and[0084] adjustment of imager parameters such as gain or intensity of LED image sensors "based on inserted tools ..." There is absolutely no basis for such a conclusion and it is, at best, speculation.

In response to such deficiencies in the rejection, the Advisory Action (mailed 8/23/2011) states that the Examiner relies on the Pronk reference for disclosing a computer that sets and controls an x-ray imaging device on patient specific information such as a body part to be examined. Appellant urges that this prior art does not at all render the claimed invention obvious because none of the prior art addresses a contrast adjustment in an image based on properties of an adjuvant (e.g., an adjuvant present in an image of, for example, a portion of a patient's body). It is only the Appellant who teaches such use of specific information relating to the adjuvant which can enhance the contrast between the adjuvant and other portions of the image.

Further, it is only the Appellant who recognizes that operating parameters for an image to be taken with an adjuvant can be associated with an identification code of the specific adjuvant. None of the other art citations compensate for the deficiencies in the Banik and Pronk references. For example, the disclosure of Malackowski as described in the rejection and in the Advisory Action does not at all relate to setting

operating parameters of the image unit according to the identification code [of the adjuvant] to control contrast

The rejection also attempts to apply the Whipple reference as though it provides disclosure in the Abstract of Whipple for

"a code [which] has instructions to control image contrast ..."

It is not seen that any disclosure relating to the bar code images described in the abstract of Whipple relate to controlling image contrast and, even if there were such disclosure, this has

nothing to do with controlling contrast between the adjuvant and surrounding regions (as asserted in the Advisory Action).

More fundamentally, the rejection is flawed because (contrary to the reassertion made in the Advisory Action) there is no motivation to combine any of this prior art in a manner which results in the claimed invention. There cannot be a legitimate combination because there is no recognition in any of the prior art of the teachings which Appellant has provided.

Instead, the rejection is a blatant attempt in hindsight to reconstruct the invention of claim 20 by suggesting that certain ones of the claimed features could be provided by the prior art. At times it appears that the Examiner is only arguing that the prior art could (if modified) perform in accord with claim 20. This is not the law on obviousness. The Examiner's speculations do not imply that one skilled in the art would have knowledge and motivation to so modify the prior art. The rejection of claim 20 should be overturned.

7B. THE REJECTION UNDER SECTION 103 OF EACH DEPENDENT CLAIM 12 – 15, 19, 21 and 24, ALSO BASED ON BANIK IN VEW OF MALACKOWSKI AND FURTHER IN VIEW OF PRONK AND STILL FURTHER IN VIEW OF WHIPPLE IS IN ERROR.

To the extent that any claim dependent claim is not separately argued herein the Board may consider that claim as rising or falling with the claim from which it depends.

7B(1) CLAIM 12 IS ALLOWABLE UNDER SECTION 103.

Claim 12 requires that the control unit combines the operating parameters associated with the identification code with data concerning the object under the medical examination. The final rejection does not appear to make any argument against patentability of this subject matter. Instead the rejection alludes to what the prior art "could" do if one skilled in the art possessed knowledge of the invention.

7B(2) CLAIM 13 IS ALLOWABLE UNDER SECTION 103.

According to claim 13, the operating parameters are stored in a memory that is accessible by the control unit. The prior art combination does not relate to storage of operating parameters

according to an identification code for an imaging unit. It is not seen that the rejection addresses this feature. Instead the rejection alludes to what the prior art "could" do if one skilled in the art possessed knowledge of the invention.

7B(3) CLAIM 21 IS ALLOWABLE UNDER SECTION 103.

Claim 21 recites that the operating parameters associated with the identification code are combined in the control unit with data concerning the object under medical examination. The final rejection does not appear to make any argument against patentability of this subject matter. Instead the rejection alludes to what the prior art "could" do if one skilled in the art possessed knowledge of the invention.

7C. THE REJECTION UNDER SECTION 103 OF EACH DEPENDENT CLAIM 16 – 17 AND 22- 23 BASED ON BANIK IN VEW OF MALACKOWSKI AND FURTHER IN VIEW OF PRONK AND STILL FURTHER IN VIEW OF WHIPPLE AND STILL, AGAIN, IN FURTHER VIEW OF BINKERT IS IN ERROR.

To the extent that any claim dependent claim is not separately argued herein the Board may consider that claim as rising or falling with the claim from which it depends.

7C(1) CLAIM 23 IS ALLOWABLE UNDER SECTION 103.

Claim 23 recites displaying a contrast agent concentration within the object in the x-ray image. None of the argument in the final office action appears to relate to this subject matter.

7D. THE REJECTION UNDER SECTION 103 OF DEPENDENT CLAIM 18 BASED ON BANIK IN VEW OF MALACKOWSKI AND FURTHER IN VIEW OF PRONK AND STILL FURTHER IN VIEW OF WHIPPLE AND STILL, AGAIN, IN FURTHER VIEW OF ANDERSONIS IN ERROR.

Claim 18 requires that a contrast agent concentration in the object is displayed via the imaging unit. None of the argument at page 4 of the final office action appears to relate to this subject matter. It is not at all understood how or why the Examiner attempts to apply the Anderson reference to reject claim 18.

7E. CONCLUSIONS

Argument has been presented to demonstrate that the rejections under Section 103 are deficient and that numerous ones of the dependent claims further distinguish over the prior art. The Examiner has argued rejections when claimed features are not obtainable from the prior art. The Examiner has also argued rejections when there is no motivation for reconstructing the invention from the prior art. For the reasons presented, there cannot be a prima facie case of obviousness and none of the rejections can be sustained. All of the rejections should be overturned and all of the claims should be allowed.

8. APPENDICES

An appendix containing a copy of the claims involved in this appeal is provided herewith. No evidence appendix or related proceedings appendix is provided because no such evidence or related proceeding is applicable to this appeal.

Respectfully submitted,

Dated: 11/23/11

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9. APPENDIX OF CLAIMS ON APPEAL

11. A medical device for taking a high energy image of an object under a medical examination into which an adjuvant is insertable, comprising:

an x-ray imaging unit for taking a high energy x-ray image of the adjuvant inserted within the object; and

a control unit which controls the taking of the high energy image, the control unit supplied with an identification code of the adjuvant via an input device and coupled to set operating parameters of the image unit according to the identification code to control contrast between the adjuvant and an adjacent region of the object in the high energy image.

12. The medical device according to Claim 11, wherein the control unit combines the operating parameters associated with the identification code with data concerning the object under the medical examination.

13. The medical device according to Claim 11, wherein the operating parameters are stored in a memory that is accessible by the control unit.

14. The medical device according to Claim 11, wherein the input device is a scanner.

15. The medical device according to Claim 14, wherein the scanner is a barcode reader.

16. The medical device according to Claim 11, wherein the medical device has an operating condition that displays the adjuvant.

17. The medical device according to Claim 11, wherein a stent and an adjacent region within the object are displayed via the imaging unit.

18. The medical device according to Claims 11, wherein a contrast agent concentration in the object is displayed via the imaging unit.

19. The medical device according to Claims 11, wherein the object is a patient.

20. A method for taking a high energy image of an object under medical examination containing a medical adjuvant, comprising:

controlling the taking of the high energy image by an imaging unit via a control unit;

inputting an identification code of the medical adjuvant into the control unit;

setting operating parameters of the imaging unit via the control unit according to the identification code; and

taking a high energy image of the adjuvant inserted and a region of the object with the imaging unit wherein the identification code is used by the control unit to control contrast between the adjuvant and the region of the object in the high energy image.

21. The method according to Claim 20, wherein the operating parameters associated with the identification code are combined in the control unit with data concerning the object under medical examination.

22. The method according to Claim 20, further comprising displaying a stent and an adjacent region within the object in an x-ray image taken by the imaging unit.

23. The method according to Claims 22, further comprising displaying a contrast agent concentration within the object in the x-ray image.

24. The method according to Claim 20, wherein the object is a patient.

10. EVIDENCE APPENDIX - 37 CFR 41.37(c) (1) (ix)

None

11. RELATED PROCEEDINGS APPENDIX - 37 CFR 41.37(c) (1) (x)

None